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In the Supreme Court of the United States

KATHLEEN SEBELIUS ET AL., *Petitioners,*
v.
HOBBY LOBBY STORES, INC., ET AL., *Respondents.*

CONESTOGA WOOD SPECIALTIES CORP., ET AL.,
Petitioners,
v.
KATHLEEN SEBELIUS, ET AL., *Respondents.*

ON WRITS OF CERTIORARI
TO THE UNITED STATES COURTS OF APPEALS
FOR THE TENTH AND THIRD CIRCUITS

BRIEF OF BEVERLY LAHAYE INSTITUTE AND JANICE SHAW CROUSE, PH.D. AS AMICI CURIAE IN SUPPORT OF HOBBY LOBBY STORES INC. AND CONESTOGA WOOD SPECIALTIES CORP., ET AL.

Catherine W. Short
Counsel of Record
Life Legal Defense Foundation
PO Box 2105
Napa, CA 92544
(707) 224-6675
LLDFOjai@cs.com
Counsel for Amici Curiae

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TABLE OF CONTENTS

TABLE OF CONTENTS i

TABLE OF AUTHORITIES iii

INTEREST OF AMICI CURIAE 1

SUMMARY OF THE ARGUMENT 2

ARGUMENT 3

I. The Government Cannot Meet its Burden Under RFRA of Demonstrating that the Mandate Furthers its Asserted Interest in Promoting the Health and Well-Being of Women 3

A. The IOM Report Does Not Support the Government's Assertion that Increased Use of Contraceptives Will Promote Women's Health. 5

1. The Government has failed to show that the Mandate will lead to increased usage among those at risk of unintended pregnancy or to a decrease in unintended pregnancies among those covered by the Mandate. 8

2. The Government has failed to show that unintended pregnancies have negative health consequences for women. 14

B. The Government Has Failed to Show that the Mandate Furthers its Asserted Interest of Promoting Gender Equity. 20

1. The Government has failed to show that the Mandate will relieve women of an inequitable financial burden related to health care.....20

2. The Government may not compel contraceptive coverage to serve a purported interest in "gender equality." 24

II. The HHS Mandate Is Not Narrowly Tailored To Serve the Health Needs of a Subset of Women With Particular Medical Problems. 25

CONCLUSION.. 28

TABLE OF AUTHORITIES

CASES

Brown v. Entm't Merchs. Ass'n., 131 S.Ct. 2729 (2011) 4, 7, 18

Eisenstadt v. Baird, 405 U.S. 438 (1972) 24

Gilardi v. U.S. Dep't of Health & Human Servs., 733 F.3d 1208 (D.C. Cir 2013) 5

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STATUTES

Certain Preventive Services under the Affordable Care Act, 77 Fed. Reg. 8725 (February 15, 2012) ..... passim

Religious Freedom Restoration Act (RFRA), 42 U.S.C. §2000 ..... 2, 3, 4, 19

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INTEREST OF AMICI CURIAE[1]

The Beverly LaHaye Institute (BLI) is the think tank and research arm of Concerned Women for America. BLI provides accurate academic and scientific data with sound analysis to inform and substantiate policy positions on contemporary issues from a traditional pro-family, pro-women perspective. Through professional research and writings, BLI stands strong in defense of marriage, women, children, and families. BLI sponsors policy forums, provides legislative testimony, compiles and analyzes social science behavioral data. Additionally, BLI publishes literature reviews, opinion editorials, reports, and monographs in an effort to advance women's well-being through sound public policy.

Janice Shaw Crouse, Ph.D., Executive Director and Senior Fellow at the Beverly LaHaye Institute, is a recognized authority on national and international cultural, children's and women's concerns. She was Woman of the Year for the international World Congress of Families 2012. She has twice served the president as an official delegate to the United Nations (2002 and 2003). Her books, *Children at Risk* (2010) and *Marriage Matters* (2012), were released by Transaction

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[1] The parties have consented to the filing of this brief, and letters of consent have been filed with the Court. No counsel for a party authored this brief in whole or in part. No party or counsel for a party contributed money intended to fund preparing or submitting this brief. No person other than *Amici* or their counsel has contributed money that was intended to fund preparing or submitting this brief.

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In this brief, *Amici* examine the evidence adduced by the Government purporting to show that the HHS preventive services mandate promotes compelling governmental interests. Amici demonstrate that the Government's facile assertion that mandating the provision of free contraceptives[2] will reduce the rate of unintended pregnancies or provide other health and societal benefits is based on flawed research and faulty logic.

SUMMARY OF THE ARGUMENT

Petitioner Conestoga Wood Specialties, Inc. and Respondent Hobby Lobby Stores, Inc. have argued that the HHS preventive services mandate requiring coverage of all FDA-approved contraceptives, including abortifacient drugs and devices ("HHS Mandate")[3], cannot meet the test of the Religious Freedom Restoration Act (RFRA), 42 U.S.C. §2000 that a governmental action imposing a substantial burden on religious exercise "further[] a compelling governmental interest."

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[2] The term "contraceptive" as used in this brief reflects terminology used by the Government in the HHS Mandate. *Amici*, however, affirm the scientific basis of Hobby Lobby and Conestoga Woods Specialties' religious objection to the capacity of some of the so-called "contraceptive" drugs and devices to terminate the life of a human being at the embryonic stage of development.

[3] *Certain Preventive Services under the Affordable Care Act*, finalized at 77 Fed. Reg. 8725 (Feb. 15, 2012.)

A close examination of the Government's evidence and arguments reveals how far short the Government has fallen from meeting its burden of demonstrating that imposition of the HHS Mandate on every health plan, whether group or individual, furthers any compelling governmental interest, particularly the most frequently asserted interests of promoting women's health and gender equity.

Amici address the logical gaps and misinformation in the Institute of Medicine Report that formed the basis for the Government's decision to impose the Mandate. *Amici* demonstrate that the purported benefits of the mandated drugs and devices rest entirely on the combined false premises that providing free contraceptives will decrease unintended pregnancies and promote gender equity, and that "unintended" pregnancies threaten women's health.

ARGUMENT

I. The Government Cannot Meet its Burden Under RFRA of Demonstrating that the Mandate Furthers its Asserted Interest in Promoting the Health and Well-Being of Women.

On August 1, 2011, pursuant to the Affordable Care Act, the Government agency known as HRSA (Health Resources and Services Administration) adopted in full the guidelines recommended by a report of the Institute of

Medicine (IOM).[4] That 2011 IOM Report recommended that no-cost "preventive services" for women include drugs and devices that Hobby Lobby and Conestoga Wood Specialties object to as gravely immoral under the teachings of their faith.

Where a government action substantially burdens religious exercise, the Government has the burden of demonstrating that the challenged regulation "furthers a compelling governmental interest." 42 U.S.C. § 2000bb-1(b). Under RFRA, "the term 'demonstrates' means meets the burden of going forward with the evidence and of persuasion." 42 U.S.C. §2000bb-2(3). The Government's burden is not met by showing hypothetical or insignificant advances in the service of its interests: "The government does not have a compelling interest in each marginal percentage point by which its goals are advanced." *Brown v. Entm't Merchs. Ass'n.*, 131 S.Ct. 2729, 2749 n.9 (2011).

The Government styles its interest as "advanc[ing] the public health, which is unquestionably a compelling governmental interest." Brief for the Petitioners at 46. However, such an interest is too "broadly formulated" for the purposes of satisfying RFRA (*Gonzales v. O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 431 (2006)), so the Government attempts to narrow it down to something involving contraceptives, but without providing a succinct formu-

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[4] Institute of Medicine, *Clinical Preventive Services For Women: Closing the Gaps* (2011) ("2011 IOM"), *available at* http://books.nap.edu/openbook.php?record_id=13181 (emphasis added).

lation. Is the Government's interest increasing access to contraceptives? Saving women money on the contraceptives they already buy? Encouraging the use of contraceptives with the goal of reducing unintended pregnancies?

The D.C. Circuit correctly described the Government's formulations of its interests as "sketchy," "highly abstract," "tenuous," "unconvincing," and "nebulous[]." *Gilardi v. U.S. Dep't of Health & Human Servs.*, 733 F.3d 1208, 1220, 1221 (D.C. Cir 2013) Even giving the Government the benefit of the doubt as to the negative health consequences for women of unintended pregnancies, "the health concerns underpinning the mandate can be variously described as legitimate, substantial, perhaps even important, but it does not rank as *compelling*, . . ." Id. at 1221 (original emphasis).

For purposes of this brief, Amici will assume that the Government's interests are 1) promoting women's health through reducing unintended pregnancies, and 2) promoting gender equity through equalization of health care costs. Like the D.C. Circuit, Amici will assume, contrary to fact, that these interests are compelling. Nonetheless, the Government's evidence that the Mandate will further these "compelling" interests falls far short of meeting its burden under RFRA.

A. The IOM Report Does Not Support the Government's Assertion that Increased Use of Contraceptives Will Promote Women's Health.

Relying entirely on the 2011 IOM Report, the Government asserts that by increasing access to contraceptives, the Mandate will promote public health by decreasing unintended pregnancies.[5]

At the risk of stating the obvious, getting pregnant is not like catching a contagious disease. Myriad factors – e.g., religion, age, marital status, social situation, medical condition, cultural background, economic circumstances– will play a part in when and whether a woman engages in sexual activity and whether, doing so, she is seeking to get pregnant, is trying to avoid pregnancy, is ambivalent about getting pregnant, or does not consider whether she will get pregnant. Thus, the Government's "vaccination model" of decreasing unintended pregnancies (i.e., assuming increased availability of contraception will decrease incidence of the "disease" of unintended pregnancy) grossly oversimplifies the issues involved.

Indeed, right from the outset, the Government's case is based on a false premise, i.e., that there is a clear distinction between intended and unintended pregnancies. In fact, "[r]esearchers have long abandoned the false dichotomy of intended versus unintended pregnancy." Some women welcome "unintended" pregnancies, and some "intended" pregnancies end in abortion due to

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[5] The Government also asserts that increased contraceptive use will promote what it contends is "healthy" birth spacing. Assuming that the Government does not intend to employ coercive measures to achieve "healthy" birth spacing, this goal can be subsumed under the more general goal of reducing unintended pregnancies.

complications or a change in a woman's social situation.[6]

Even assuming arguendo that there is a clear-cut, measurable category of pregnancies that are "unintended," the Government has failed to demonstrate that 1) lowering the costs of contraceptives (to zero) for those covered by insurance will lead to any appreciable increased usage among those currently at risk of unintended pregnancy within that population and to a decrease in unintended pregnancies within that population, and 2) unintended pregnancies have negative health consequences for women. Rather, the Government's argument is based on a chain of presumed causes and effects, and the evidence supporting each link is attenuated, ambiguous, disputed, or non-existent. Indeed, "[n]early all of the research is based on correlation, not evidence of causation, and most of the studies suffer from significant, admitted flaws in methodology." *Brown, supra,* 131 S.Ct. at 2739 (quotation marks omitted).

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[6] Harvey, Jacqueline C., *Outdated Lexicons and obsolete solutions: A response to the editorial in the February 2013 issue of Contraception,* Reproductive Research Audit (February 12, 2013), *available at* http://reproductive researchaudit.com/wpcontent/uploads/2013/02/Pregnancy-Ambivalence-1.pdf. *See also* Trussell, J., Vaughn, B. & Stanford, J., *Are All Contraceptive Failures Unintended Pregnancies? Evidence from the 1995 National Survey of Family Growth,* Family Planning Perspectives, 31(5) (1999).

1. The Government has failed to show that the Mandate will lead to increased usage among those at risk of unintended pregnancy or to a decrease in unintended pregnancies among those covered by the Mandate.

The Government hypothesizes that women are deterred from obtaining contraceptives because of their cost, and that therefore the Mandate will increase utilization of contraceptives. However, its evidence is based on supposition, dubious analogies, and assumed but unproven correlations.

The IOM Report cites a Kaiser Family Foundation report as evidence that women are more likely than men to report cost-related barriers to receiving medical care. The study in question asked men and women whether they *or a family member* had delayed or foregone certain health care in the past year because of the cost.[7] Thus, the fact that more women than men, by a factor of a few percentage points, reported they *or a family member* had done so says little about which gender is actually foregoing medical care because of the cost.

The IOM also cites studies showing that the costs of cancer screening, dental services, mammograms and pap smears may deter women

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[7] Focus on Health Reform. *Impact of health reform on women's access to coverage and care*. Washington, DC: Henry J. Kaiser Family Foundation (2010), *available at* http://www.kff.org/womenshealth/ upload/7987.pdf.

from receiving those services.[8] Yet, even if these studies in fact supported the IOM's statement,[9] none of them makes the necessary connection between women deferring or foregoing this type of care (i.e., screening tests) and women failing to buy contraceptives because of the cost. It is far from a logical corollary that a woman who delays getting her annual pap smear because of the cost will also decide to stop using contraceptives because of the cost.

Regarding contraceptives in particular, the IOM's own sources show that 89% of women avoiding pregnancy are already practicing contraception,[10] and that among the other 11%, lack of access is not a statistically significant reason why they do not contracept.[11]

The IOM's citation to a study by Santelli and Melnikas in support of its argument that increased use of contraceptives will lead to declines in the rate of unintended pregnancy is typical of its

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[8] 2011 IOM at 19.

[9] One of the two studies cited for the proposition that women forego mammograms and pap smears because of the cost (2011 IOM at 19) has nothing to do with that topic. Trivedi, A. N., H. Moloo, and V. Mor. 2010. *Increased ambulatory care copayments and hospitalizations among the elderly.* New England Journal of Medicine 362(4):320–328.

[10] The Guttmacher Institute, *Facts on Contraceptive Use in the United States* (June 2010), *available at* http://www.guttmacher.org/pubs/fb_contr_use.html (last visited September 20, 2012).

[11] Mosher WD and Jones J, *Use of contraception in the United States: 1982–2008, Vital and Health Statistics* (2010) Series 23, No. 29, at 14 and Table E, *available at* http://www.cdc.gov/NCHS/data/series/ sr_23/sr23_029.pdf.

approach to this topic.[12] The Santelli study examined, *inter alia*, whether increased **use** of contraception by **teens** was associated with decreased pregnancies. Thus, the study is based on increased usage, a factor that the IOM failed to establish will result from the Mandate, because it failed to prove that cost was a deterrent factor to contraceptive use. Second, the study was limited to teens, a subgroup far narrower than and differing in significant ways from the group affected by the Mandate.[13]

Indeed, this failure to consider the particular demographic involved is a common flaw in the studies cited by the IOM and other defenders of the Mandate. Being limited to, e.g., teens or poor women, these studies lack probative value on the effect of the Mandate on the demographic at issue: employed women, the wives of employed men, and the female dependents of employed parents.

Undeterred, the IOM Report concludes, "The elimination of cost-sharing for contraception therefore could greatly increase its use, including use of the more effective and long-acting methods, especially among poor and low-income women most

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[12] Santelli, J. S., and A. J. Melnikas. 2010. *Teen fertility in transition: Recent and historic trends in the United States.* Annual Review of Public Health 31:371–383.

[13] Having found that many other factors contributed to the observed decline in the teen pregnancy rate over the applicable time period, the authors specifically disclaimed the intent to "resolve this debate" over the causes of teen pregnancy. *Id.* at 379-380. Even less so, then, should their study be used as a prescription for "resolving" the debate over whether increased access to contraception will reduce unplanned pregnancies among other demographic groups.

at risk for unintended pregnancy."[14] The final logical lapse in the IOM's treatment of this topic is that poor and low-income women are already eligible to receive no-cost contraceptives under myriad state and federal programs.[15] Yet, as the Report itself notes, they have significantly higher rates of unintended pregnancy than that part of the female population not guaranteed free contraceptives.

The IOM Report, and similarly the Government, seems oblivious to the lessons learned over the five decades since the advent of hormonal contraceptives, namely, that while for the individual, a contraceptive drug or device may prevent a pregnancy, this result cannot be extrapolated to a societal scale. Increasing access to contraceptives affects not only those who were already at risk for unintended pregnancy. Rather, it changes behaviors and expectations across society.

For example, Duke University Professor Peter Arcidiacono found that data from the 1997 National Longitudinal survey of Youth suggested that while access to contraception decreases teen pregnancy in the short run, it increases teen pregnancy in the long run by encouraging sexual activity.[16] Multiple studies have analyzed the

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[14] 2011 IOM at 109.

[15] 2011 IOM at 108.

[16] P. Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* Working Paper, Duke Univ. Dept. of Economics (Oct. 3, 2005), *available at* http://public.econ.duke.edu/~psarcidi/ teensex.pdf.

effect of access to emergency contraception (EC) on pregnancy and abortion rates. Not only have ECs failed to lower teen pregnancy rates according to every relevant study in myriad countries, but they are disturbingly and regularly associated with increases in teen pregnancy and abortion rates.[17] In two studies conducted in 2000 and 2005, teens admitted to researchers that they "had been more careless about birth control and more likely to have had unprotected sex."[18]

Emergency contraceptives appear similarly ineffective at reducing unintended pregnancies for the general population. A meta-analysis of 23 studies evaluating the effectiveness of Plan B concluded that "*no study* has shown that increased access to [Plan B] reduces unintended pregnancy or abortion rates on a population level."[19]

A Guttmacher Institute report on unintended pregnancy between 2001 and 2006, concluded that changes in contraceptive method and

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[17] J. Duenas, et al., *Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population during 1997-2007*, 83 Contraception 82 (2011) (over ten year period, 63% increase in contraceptive use accompanied by a 108% increase in the abortion rate); D. Paton, *The Economics of Family Planning and Underage Conceptions*, 21 J. of Health Economics, 207 (2002).

[18] Roni Caryn Rabin, *Teenagers and the Morning After Pill*, The New York Times, Dec 3, 2012, *available at* http://well.blogs.nytimes.com /2012/12/03/teenagers-and-the-morning-after-pill/?ref=ronicarynrabin.

[19] Elizabeth G. Raymond, James Trussel & Chelsea B. Polis, *Population Effect of Increased Access to Emergency Contraceptive Pills: A Systematic Review*, 109 Obstetrics & Gynecology 181 (2007).

use did not decrease the overall proportion of pregnancies that were unintended, despite CDC data showing that more women in the years between 2002 and 2008 were accessing methods of contraception deemed "more effective" by the IOM, the CDC and Guttmacher.[20]

Considering a broader perspective, in 1972 an estimated 35.4% of pregnancies in the United States were unintended.[21] Medicaid has, since 1972, required coverage for contraceptives in all state programs and has exempted the drugs from cost-sharing requirements. Over half the states now also operate Medicaid-funded contraceptive programs for low-income women who exceed Medicaid's income guidelines. Following suit, most private employers now include contraceptive coverage in their plans, and 28 states require private employers to cover contraceptives.[22]

The 2011 IOM Report places the current rate of unintended pregnancy at 49%.[23] This 40% increase since 1972 has occurred despite – or possibly because of – multiple programs and policies operating on the same premise as the HHS Mandate does, namely, that lowering or erasing the

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[20] Lawrence Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: incidence and disparities, 2006*, 84 Contraception 478 (2011).

[21] Christopher Tietze, *Unintended Pregnancies in the United States, 1970-1972*, 11 Fam. Planning Perspectives 186 (1979).

[22] 2011 IOM at 108.

[23] 2011 IOM at 102.

cost of contraceptives will decrease unintended pregnancies.[24]

The Government has signally failed to show that the Mandate, by forcing all health plans to provide contraceptives at no cost, will further the asserted governmental interest in promoting women's health through decreasing unintended pregnancies.

2. The Government has failed to show that unintended pregnancies have negative health consequences for women.

The IOM admits that for many negative outcomes from unintended pregnancy, "research is limited."[25] The IOM cites its 1995 report, which similarly emphasizes the fundamental difficulty in defining which pregnancies are "unintended," and in distinguishing between association and causation in assessing the risks of unintended

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[24] The IOM also states that 42% of these unintended pregnancies end in abortion, i.e., 21% of all pregnancies. 2011 IOM at 102. Assuming that accidental loss of pregnancy is evenly distributed among intended and unintended pregnancies, the IOM's statistics mean that the 28% of pregnancies that are unintended and carried to term make up about 35% of all births in the U.S. (28% [percent of all pregnancies that are unintended and carried to term] divided by 78% [percent of all pregnancies carried to term]). Thus, the Government's goal of reducing the numbers of unintended pregnancies, presumably to zero, without any concomitant effort to increase the number of intended pregnancies and births, would plunge the United States into a steep demographic decline.

[25] 2011 IOM at 103.

pregnancies.[26]

The 1995 IOM Report concedes that no causal link has been established for most of its alleged factors. This makes sense, since a pregnancy's status as intended or unintended cannot itself physiologically change the pregnancy's health effect. Thus, a delay in seeking prenatal care for an unintended pregnancy may be "no longer statistically significant" for women who are not already disposed to delay or who have a "support network,"[27] – as do Hobby Lobby and Conestoga Wood Specialties' insured employees, as well as the employees' spouses and dependents.

The IOM Report cites to other behavioral risk factors linked with unintended pregnancy, including smoking, drinking, depression, and domestic violence.[28] However, it is impossible to say, and the IOM Report does not attempt to prove, that unintended pregnancy leads to these negative behaviors and unhealthy situations. Rather, the linkage between them and unintended pregnancy is in many cases likely to be one of association, not causation.

For example, on the topic of depression, the IOM Report cites a 2008 meta-analysis, but fails to reveal that the study's authors concluded there that, due to the "paucity of studies investigating the impact of unintended pregnancy on psychosocial health and well being, and their

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[26] Institute of Medicine, *The Best Intentions* (1995) ("1995 IOM"), *available at* http://books.nap.edu/openbook.php?Record_id=4903&page=64 (last visited September 20, 2012).

[27] *Id.* at 68.

[28] 2011 IOM at 103.

limitations in terms of establishing causality, the existing research should only be considered to be *suggestive* of such an impact." [29] This study also states that all research regarding the "effects" of unintended pregnancies on mothers' health is "plague[d] by the problem of establishing causality between unintended pregnancy and subsequent health outcomes," and that "*causality is difficult if not impossible to show.*"[30]

Further, the preventive services recommended by the U.S. Preventive Services Task Force, already required by the ACA to be provided without a co-pay, include counseling for pregnant women concerning smoking and drinking, while domestic-violence prevention is a separately recommended preventive service for women within the 2011 IOM Report itself.[31]

The IOM's suggestion that increased access to contraceptives will reduce low birth weight and prematurity overlooks the fact that, like other cited factors, these are merely "associated" with, not caused by, unintended pregnancy (2011 IOM at 103; 1995 IOM at 70); the IOM itself cites studies showing no connection between low birth weight and pregnancy-spacing in the U.S.[32]

Notably, the 2011 IOM Report claims to cite a systematic review on low birth weight, but the

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[29] Gipson, J. D., M. A. Koenig, and M. J. Hindin, *The effects of unintended pregnancy on infant, child, and parental health: A review of the literature*, 39 *Studies in Family Planning* 18 (2008) (emphasis added).

[30] *Id.* (emphasis added).

[31] 2011 IOM at 117.

[32] 1995 IOM at 70-71.

citation is incorrect.[33] The IOM Report then cites three studies showing an association between low birth weight/preterm delivery and shorter pregnancy intervals.[34] The IOM Report fails to note that all three studies found these same negative outcomes for lengthy pregnancy intervals, a condition likely to follow upon increased contraceptive use.[35]

Also absent from the IOM's discussion of low birth weight and prematurity is any measure of how detrimental these conditions are for newborns in terms of immediate or long-term health effects. Assuming arguendo some (unstated) percentage of unplanned pregnancies were shown to result in premature or low-birth weight babies, the IOM Report provides no information as to what percentage of these babies will require significant medical intervention or suffer long-term consequences. "The government does not have a

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[33] 2011 IOM at 103, 166 (citing "Shah, et al., 2008"). The Shah study does not address low birth weight; it was study of cardiovascular disease in young women with gestational diabetes. B.R. Shah, R. Retnakaran, and G. L. Booth, *Increased risk of cardiovascular disease in young women following gestational diabetes mellitus*, 31(8) Diabetes Care 1668 (2008).

[34] *Id.* at 103.

[35] The IOM also failed to consider the risks of low birth weight that arise from contraceptive use itself: a 2009 Canadian study shows that women who conceive within 30 days of going off contraceptives significantly increase the risk of low birth weight and very low birth weight. Chen, et al., *Recent oral contraceptive use and adverse birth outcomes*, 144 *European Journal of Obstetrics & Gynecology and Reproductive Biology* 40–43 (May 2009), *abstract available at* http://www.ejog.org/article/S0301-2115(09)00074-8/.

compelling interest in each marginal percentage point by which its goals are advanced." *Brown*, *supra*, 131 S.Ct. at 2749 n.9.

More importantly, however, the IOM makes no attempt to link these alleged negative outcomes of unplanned pregnancy with women's health. The IOM was tasked with making recommendations for women's health, not children's health.[36] "The Institute of Medicine will convene an expert committee to review *what preventive services are necessary for women's health and well-being* and should be considered in the development of comprehensive guidelines for preventive services for women."[37] Thus, unless the Government can point to evidence in the record that caring for children is detrimental to women's health and well-being, the IOM Report's discussion of the purported negative effects of unintended pregnancy on the health of children born of such pregnancies is outside the scope of its mission to recommend specific preventive services to promote women's health.[38]

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[36] One lower court noted the "somewhat odd implication by the Government that the *use* of contraception could somehow have a beneficial impact on a 'developing fetus' that contraceptive use is itself designed to avoid, . . ." *Legatus v. Sebelius*, 2012 U.S. Dist. LEXIS 156144, 2012 WL 5359630 (E.D. Mich., Oct. 31, 2012) (original emphasis).

[37] Office of Secretary, Statement of Task to the Committee on Preventive Services for Women, reprinted at 2011 IOM at 2 (emphasis added).

[38] If the Government intends to broaden the definition of "women's health and well-being," and thus the goal of the Mandate, to include non-health related concepts such as emotional well-being and economic prosperity, then it should likewise have considered the documented negative effects the

In sum, while the Government's general interest in "preventive services" for "women's health and well-being" may be valid, its act of coercing religiously objecting employers and individuals to pay for coverage for drugs that significantly increase risks to women's health,[39] while providing dubious health benefits, certainly fails to further that interest. As explained by the U.S. Supreme Court, "We do not doubt the validity of these interests, any more than we doubt the general interest in promoting public health and safety. . . but under RFRA **invocation of such general interests, standing alone, is not**

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widespread availability of contraceptives has on women's ability to enter into and maintain desired marital relationships. This in turn leads to decreased emotional well-being and economic stability (out-of-wedlock childbearing being a chief predictor of female poverty), as well as deleterious physical health consequences arising from, *inter alia*, sexually transmitted infections and domestic violence. *See, e.g.*, George A. Akerlof, Janet L. Yellen & Michael L. Katz, *An Analysis of Out-of-Wedlock Childbearing in the United States*, 111 The Quarterly J. of Econ. 277 (1996); Timothy Reichert, *Bitter Pill*, First Things (May 2010) 25; Jonathan Klick & Thomas Stratmann, *The Effect of Abortion Legalization on Sexual Behavior: Evidence from Sexually Transmitted Diseases*, 32 J. of Legal Studies 407, 431-32 (2003) (citations omitted); Jackson, Nicky Ali, *Observational Experiences of Intrapersonal Conflict and Teenage Victimization: A Comparative Study among Spouses and Cohabitors*, 11:3 Journal of Family Violence at 191-203 (1996) ("regardless of methodology . . . cohabitors engage in more violence than spouses").

[39] See Brief of *Amici Curiae* Breast Cancer Prevention Institute, et al.

enough." *Gonzales v. O Centro, supra*, 546 U.S. at 438 (2006) (emphasis added).

B. The Government Has Failed to Show that the Mandate Furthers its Asserted Interest of Promoting Gender Equity.

1. The Government has failed to show that the Mandate will relieve women of an inequitable financial burden related to health care.

The Government asserts another allegedly compelling governmental interest, namely, promoting gender equity by removing the unequal financial barriers to health care, specifically preventive care, that arise from higher out-of-pocket costs for women's gender-specific conditions. The Government asserts that relieving women of the alleged disparity in costs will lead to equal access to health care, better health, and therefore equal opportunities to participate in the workplace with men. Underlying this argument are a number of premises for which the Government has provided little or no supporting evidence.

First, as set forth in the preceding sections, the Government has failed to show that the Mandate will in fact improve women's health. Indeed, there is substantial evidence that widespread and lengthy use of contraceptives by women has resulted and will result in significant

harm to their health.[40] This in and of itself disposes of the Government's alleged "gender equity" interest. If free contraceptives do not in fact promote women's health, they do not promote the Government's asserted interest in gender equity through equalization of the costs of maintaining health.

Even assuming *arguendo* that contraceptives in some measure promote women's health, the evidence presented by the Government to support its premise that women are inequitably burdened by their costs is woefully inadequate.

The Government cites the IOM Report for the proposition that women incur more in out-of-pocket costs for preventive care than men do, owing to reproductive and gender-specific conditions.[41] There are two problems with this "evidence."

First, the two sources cited by the IOM do not support the statement. The first study does not discuss out-of-pocket expenses at all. It compared, by gender, rates of primary care office visits, referrals, and hospitalizations.[42] The second study was focused on "the effect of the lack of health insurance on health care utilization for female-specific conditions." The "female-specific conditions" studied were specific disorders and pathologies, not

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[40] The Government itself admits that hormonal contraceptives are "sometimes associated with side effects such as high blood pressure, blood clots, heart attacks, or strokes." Brief for the Petitioners, in *Sebelius v. Hobby Lobby Stores, Inc.*, at 48.

[41] 2011 IOM at 19.

[42] Bertakis, K. D., R. Azari, L. J. Helms, E. J. Callahan, and J. A. Robbins, *Gender differences in the utilization of health care services*, 42 Journal of Family Practice 147 (2000).

preventive care.[43] Neither of these studies even identifies contraceptives as a health care cost, much less attempts to quantify to what extent contraceptive coverage contributes to increased health care costs for women.

Second, the assertion that women incur greater out-of-pocket expenses for preventive care than men (77 Fed. Reg. 8725, 8728) omits a crucial piece of information: out of *whose* pocket?

Three categories of women would receive contraceptives at no cost under the Mandate: covered employees, the wives of covered employees, and the female dependent children of covered employees.

There is no reason to believe the out-of-pocket health care expenses of the wives of covered employees are currently being borne solely by them, rather than being a shared household expense, just as the groceries are. Similarly, the out-of-pocket expenses of the female dependents of the covered persons are presumptively being borne by the persons on whom they are *dependent*. Thus, for spouses and dependents, the Mandate does not relieve women of a burden unequally shared with men. Rather, it shifts a burden from the covered person's household onto others, either an employer or other persons insured in the same pool. As such, it does nothing to further Government's asserted interest in gender equity.

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[43] Kjerulff, K. H., K. D. Frick, J. A. Rhoades, and C. S. Hollenbeak, *The cost of being a woman—a national study of health care utilization and expenditures for female-specific conditions*, 17 Women's Health Issues 13 (2007).

In the case of a covered person herself, the Government simply assumes that her out-of-pocket health care expenses are borne by her alone. However, considering in particular the out-of-pocket expenses for contraceptives, the need for contraceptives indicates she has some intimate relationship with a man, quite possibly her husband. The Government apparently assumes without proof that men – whether husbands, roommates, or in some other role – in intimate relationships with women do not contribute to the costs of whatever contraceptive method is used by the couple. But without such proof, there is no reason to believe that women are carrying an inequitable burden when it comes to the costs of contraceptives nor, consequently, that the Mandate does anything but shift the financial burden of contraceptives, not from the woman, but from the couple onto others – again, doing nothing to further the asserted governmental interest in promoting gender equity. [44]

In sum, the Government has failed to carry its burden of proving that the coercive Mandate **in fact**, not in theory, furthers its asserted interest in promoting women's health or gender equity.

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[44] At this point in the discussion, it is virtually impossible to concede, even for the sake of argument, that the Government's interest is compelling. Even if the Government could prove that covered women employees are bearing the full costs of their contraceptives, it is difficult to credit that the Government has a *compelling* interest in guaranteeing free contraceptives for women who sleep with men who will not contribute to the cost of their birth control.

2. The Government may not compel contraceptive coverage to serve a purported interest in "gender equality."

The Government has also extrapolated from the interest in "gender equity" in health care costs yet another interest purportedly justifying the Mandate, that of promoting "a woman's control over her procreation." In defending the Mandate below, the Government argued that this interest is "so compelling as to be constitutionally protected from state interference." See, e.g., Brief for the Appellees, *Hobby Lobby et al. v. Sebelius*, at 34-35; Brief for the Appellees, *Conestoga Wood Specialties, Inc. v. Sebelius*, at 34-35. (citing *Eisenstadt v. Baird*, 405 U.S. 438 (1972) and *Griswold v. Connecticut*, 381 U.S. 479 (1965).). This argument is unavailing for several reasons.

First, this interest is found nowhere in the legislative history or language of the Women's *Health* Amendment, an amendment to the *Affordable Care* Act, the only legislative authorization for the Mandate. There is no evidence in the legislative record of either the ACA or the Women's Health Amendment from which the Government could argue that Congress intended to increase access to contraceptives for the sake of assisting women in being able to avoid pregnancy and childbearing as an end in itself ("controlling her own procreation"). Rather, the legislative history shows that Congress's intent was to relieve

women of certain inequitable financial burdens they face in maintaining their health.[45]

Second, it is a *non sequitur* to contend that, because a right is protected from governmental interference, the government therefore has a "compelling interest" in furthering the exercise that right. For example, the Government cannot interfere in a person's right to read pornography, but this does not mean that the Government has a compelling interest in assisting people to obtain and read pornography.

Third, the Government's argument fallaciously equates "interference" with the exercise of a constitutional right, with declining to fund the exercise of that right. The Government itself is not required to fund a woman's exercise of "right to control her procreation." *Harris v. McRae*, 448 U.S. 297 (1980) (upholding federal ban on abortion funding). Much less does the Government have a compelling interest in forcing others to fund the exercise of that right.

II. The HHS Mandate Is Not Narrowly Tailored To Serve the Health Needs of a Subset of Women With Particular Medical Problems.

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[45] Sen. Barbara Mikulski, who offered the Women's Health Amendment, stated on the floor of the Senate, "This amendment is strictly concerned with ensuring that women get the kind of preventive screenings and treatment they may need to prevent diseases particular to women such as breast cancer and cervical cancer." Cong. Rec. S12274 (daily ed. Dec. 3, 2009).

The Government, citing the IOM Report, argues that the Mandate also serves the compelling interesting in promoting women's health because some women have medical conditions for which pregnancy in some circumstances may be contraindicated.

This argument ignores the fact that these women comprise a far smaller group than the Mandate covers, and for that reason, the Mandate as currently structured is not narrowly tailored. For example, the Government and the IOM Report cite women with Marfan Syndrome as falling into this category of women who need access to contraceptives because of specific medical conditions. However, only about one in 6,000 to 10,000 women in the United States have Marfan Syndrome.[46] The percentage is even smaller when considering only sexually active women in their childbearing years.

The Mandate is premised on the supposed general need of women for access to contraception as "preventive" care. The argument from Marfan syndrome, lupus, pulmonary hypertension, and similar conditions does not address this premise. These conditions are rare; moreover, they create and/or are part of a whole complex of health-related concerns for the women who have them, which may or may not necessitate avoiding pregnancy if the women are sexually active. Contraceptives are not "preventive" care for these women; these drugs are not preventing or detecting the onset of any

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[46] Keane MG, Pyeritz RE, *Medical management of Marfan syndrome*, 117 (21) Circulation 2802–13. (May 2008).

disease. To the extent that the underlying diseases necessitate pregnancy avoidance, a prescription of contraceptive drugs for this purpose would be more akin to a prescription of medication to control blood pressure or reduce joint swelling, neither of which are considered regular "preventive" care under the ACA.

Moreover, the IOM Report appears oblivious to the fact that the very conditions it uses to illustrate why some women need to postpone pregnancy (e.g., diabetes, obesity, pulmonary hypertension) and therefore to justify its recommendation to facilitate access to contraception, are the same conditions that put women at greatly increased risk for cardiovascular problems from contraceptive use. Focused health care to treat women with these conditions -- health care already covered in Hobby Lobby's and Conestoga Wood Specialties' plans -- will better achieve the Mandate's goals of promoting women's health.

The IOM Report also asserts that contraceptives have other health benefits unrelated to preventing pregnancy, such as treating acne, hirsutism, menstrual disorders, and pelvic pain.[47] However, any such other effects are irrelevant to the premise of the Mandate of providing specific "preventive" care at no cost to promote women's health. If Congress had considered acne, hirsutism, or other conditions serious and/or common and/or expensive enough to warrant no-cost coverage of drugs to treat them, whether contraceptive or

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[47] 2011 IOM at 107.

otherwise, it could have so provided. It did not. Therefore, the fact that contraceptives **might** be used to treat these conditions does not bolster the Government's argument that there is a compelling governmental interest in including contraceptives as part of the preventive care mandate.

Universal coverage of contraceptives drugs with no co-pay as "preventive" care is not a narrowly tailored means of dealing with the unusual medical situations posited by the Government.

CONCLUSION

For the foregoing reasons, *Amici* request that this Court affirm the Tenth Circuit's grant of injunctive relief to Respondent Hobby Lobby and reverse the Third Circuit's denial of injunctive relief and remand with instructions to enter an injunction as requested by Petitioner Conestoga Wood Specialties.

Respectfully submitted,

Catherine W. Short
Counsel of Record
LIFE LEGAL DEFENSE FOUNDATION
P.O. Box 1313
Ojai, CA 93023
Tel: (805) 640-1940
Fax: (707) 224-6676
LLDFOjai@cs.com
Counsel for Amici Curiae